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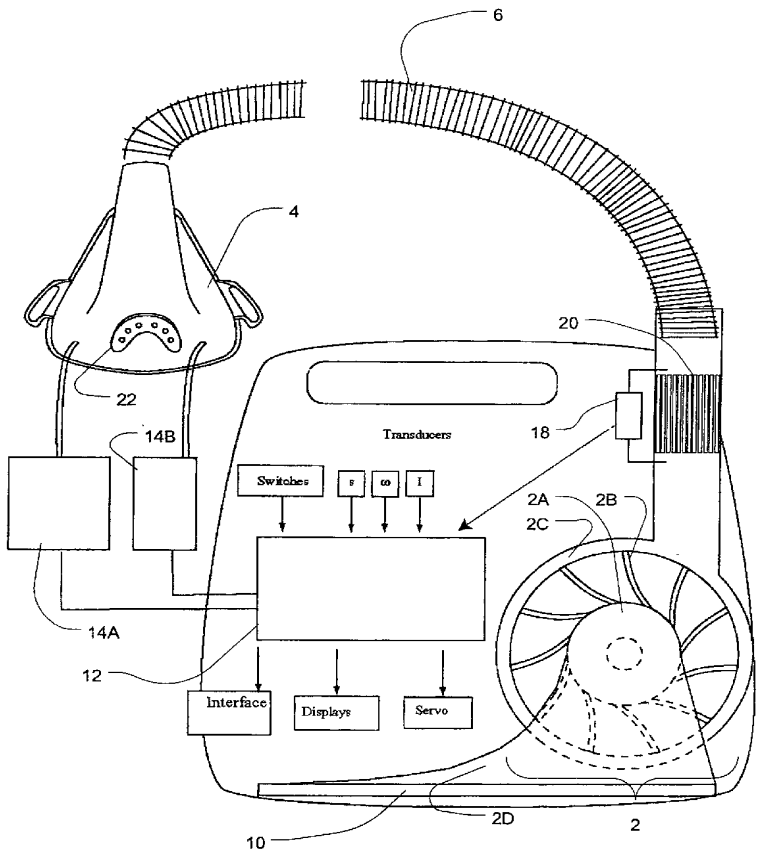
(54) Title: METHODS AND APPARATUS FOR SUPPLYING CLEAN BREATHABLE GAS



(57) Abstract: The invention features methods and apparatus for the treatment of asthma patients. A controlled supply of breathable air delivered to a patient interface or mask (4) is controlled for patient comfort to maintain a steady pressure level in a range 2 to 4 cm H2O to accommodate patient respiration. The breathable air is cleaned by a high efficiency particulate arresting filter (10) to remove allergens from the air supply. The apparatus may be programmed to automatically detect asthma-related symptoms such as an asthma attack by analyzing the respiratory flow of the patient. In response to the detection of such an attack, the apparatus may provide an audible warning or if configured with a treatment delivery module (14A, 14B), the device may administer a therapeutically effective dose of a drug or substance, for example, a broncho-dilator, to alleviate the patient's breathing difficulty. Preferred mask designs allow for proper CO2 washout to accommodate the low pressures supplied to the mask and prevent asphyxia.

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METHODS AND APPARATUS FOR SUPPLYING CLEAN BREATHABLE GAS

This application claims the priority filing date of Australian provisional patent application serial number PR3154 filed on February 16, 2001.

Field of the Invention

The invention relates to a method and apparatus for providing a supply of clean breathable gas particularly during sleep. More specifically, the invention relates to devices that may be used to detect, diagnose, treat, manage and/or prevent asthma symptoms in patients.

Background of the Invention

The presence of airborne particles such as pollen, fungal spores and dust mites in bedrooms is associated with respiratory diseases such as asthma. The United States National Institutes of Health (NIH) recommends removing such things as pets, rugs, carpets and curtains to reduce the presence of allergens in the bedroom (NIEHS Fact Sheet #9, ASTHMA, 7/97). A known solution is to place an air filter in the bedroom such as the Austin Healthmate which includes HEPA (High Efficiency Particulate Arresting) filters and activated carbon. HEPA technology is described in US Patent Serial Nos. 4,629,482, 4,685,944 and 6,289,974. Such air filters are provided as free-standing units as shown in Fig. 1. These devices are said to clean the air in a typical sized bedroom in 15 to 30 minutes. Known problems with such devices include that they can be too noisy to run continuously while a person is attempting to sleep in the same room, as well as the possibility of the room becoming recontaminated every time that the door, windows or ventilation ducts are opened.

A known acute therapy for asthma is oral delivery of a broncho-dilator such as albuterol (also known as salbutamol). One form of this drug is Ventolin™ manufactured by SmithKline Beecham. Another example of a therapy used for the treatment of asthma is the delivery of a vasodilator such as a therapeutically effective amount of nitric oxide as disclosed in U.S. Patent Serial No. 5,873,359.

Summary of the Invention

The invention features an apparatus for providing a supply of clean breathable gas that is designed for those who suffer from asthma. The apparatus includes a blower with an allergen filter, such as a HEPA filter, an air delivery conduit and a patient interface, and may be conveniently designed for portable or outpatient use. The blower provides air to the patient interface at a preferred range of pressure from 1 to 4 cm H_2O. The blower includes a flow meter for monitoring the flow of air to and from the patient. The apparatus may include a controller such as a microprocessor for analyzing the flow signal to determine asthma-related symptoms, for example, by calculating an index of roundness or flatness of the flow curve, or both, which may be indicative of the bronchial hyperactivity that characterizes asthma or partial obstruction of the airways. The device also monitors the tidal volume of the patient's respiration. The device may include an alarm for alerting the patient or a care-giver that the person using the device may be suffering an asthma attack. In another embodiment, the device includes apparatus for delivering to the patient a dose of a therapeutic drug or other therapeutically-effective substance. In one form, the delivery of oxygen or other therapeutic substance is synchronized with the inspiratory phase of the breathing cycle.

Brief Description of the Drawings

Fig. 1 shows a prior art device for air filtration;

Fig. 2 shows one embodiment of an apparatus according to the invention;

Fig. 3 depicts a porous mask suitable for use with the invention;

Fig. 4 illustrates another patient interface having a porous portion for use with the invention;

Fig. 5 depicts another patient interface designed in accordance with the goals of the invention;

Fig. 6 illustrates the positioning of the mask of Fig. 5 on a user.

Detailed Description of the Invention

As illustrated in Fig 2., the asthma treatment/prevention apparatus of the invention includes a blower or other similar device to generate a flow of breathable gas

under pressure to a user. The blower 2 supplies breathable gas, such as air, to a patient interface 4, e.g. a mask, via an air delivery conduit 6 as shown in Fig. 2. An example of a suitable blower can be either the RESMED S6™ and S7™ blowers (ResMed Limited). Another suitable blower is found in the AUTOSET T™ and AUTOSET SPIRIT™ devices (ResMed Limited). The blower consists of an electric motor 2A connected to an impeller 2B, the impeller being housed in a suitable volute 2C, for example as described in PCT/AU99/00444.

The blower 2 is designed to have a rising fan curve. This means that as the flow increases, the pressure delivered by the blower increases so as the patient progresses through each cycle of inhalation and exhalation, the mask pressure remains relatively constant. Alternatively, the blower may be process controlled by a controller to implement such a regulation of the mask pressure.

In one form of the invention, the blower motor 2A is a mains voltage AC motor. In this case a power transformer would not be required, reducing the cost of the device. The use of such a motor would dictate a larger impeller than would be the case where the blower uses a lower than mains voltage AC motor or a DC motor. Alternatively, a multistage impeller could be used with the AC motor.

The flow rate must exceed the minimum requirements of breathing to ensure adequate CO_2 washout from the patient interface 4. A typical normal patient might have a tidal volume of 0.5 L and a breathing frequency of 10 to 15 breaths per minute. Hence the apparatus must deliver in excess of approximately 10 L/min. In order to allow for coughs or sighs, the flow rate may be several multiples of the minimum breathing requirements. However, the desired CO_2 washout flow may dictate a higher flow. In one particularly preferred form, the apparatus is designed to have a minimum washout flow of 25 litres/min. The blower 2 of the apparatus in conjunction with the patient interface 4 has the capacity to deliver sufficient flow in an approximate pressure range of 1 cm H_2O to 4 cm H_2O above ambient pressure.

In accordance with the present invention the device may also vary the pressure delivered in the mask from inspiration to expiration (lower for expiration) to assist with the ventilation. A suitable device for this purpose is the VPAP™ positive pressure nasal ventilation device by ResMed Limited. Typically the expiratory pressure (i.e. the mask

pressure during expiration) would be set to achieve adequate CO_2 washout while the inspiration pressure (i.e. the mask pressure during inspiration) would be set to provide the requisite level of ventilatory assistance. In addition the automatic ventilatory control may be applied to expiration pressure by adopting the techniques taught in U.S. Patent Serial No. 5,704,345.

Such ventilatory control in the application of the automatic system will monitor and track the patient's ventilation and increase the level of ventilation support when low ventilation is detected based on a continuously updated template of medium term ventilation. Examples of techniques for monitoring ventilation and determining the appropriate ventilatory assist response can be found in PCT/AU97/00631 Berthon-Jones assignee ResMed Limited.

Preferably, the breathable gas that is supplied by the apparatus is substantially free of allergen particles or other asthma symptom-inducing particulates or pollutants. Where ambient air is supplied through the blower 2, the capacity for removing asthma symptom-inducing particulates is provided. Preferably this capacity is provided to function in conjunction with the blower 2 or it may be externally adapted thereto. For example, the blower inlet 2D may include an air cleaning device 10 or filter designed to remove allergens from the ambient air. The air cleaning device 10 or filter may also be designed to remove other air pollutants or particulates. Known air cleaning devices include mechanical filters, electronic filters, hybrid filters (mechanical/electrostatic filters), gas phase filters or ozone generators. A preferred example of a suitable filter for use in the invention is a HEPA filter, alone or in combination with activated carbon. It is generally accepted that a HEPA filter will remove 99.97 percent of airborne particles having a size of 0.3 microns or larger.

The air delivery conduit 6 may be a gas delivery tubing as commonly used with CPAP devices having a cross-sectional diameter of approximately 22cm. In conventional CPAP treatment it has become generally accepted that a gas delivery tube of at least 22cm cross-sectional diameter is required to minimize mask pressure swings to a clinically acceptable extent. The pressure swings occur as the patient inhales and exhales. An embodiment of the present invention may operate within a mask pressure range that is typically less than that used in conventional CPAP for the treatment of

obstructive sleep apnea. For example the pressure range may be between 1.75cm H_2O and 2.5 cm H_2O. In view of this lower mask pressure range used in an embodiment of the present invention it is less susceptible to clinically significant mask pressure swings. In embodiments of the present invention any pressure drop is not of significance so long as the final pressure near the wearer's nose and/or mouth remains slightly above the ambient pressure. In another embodiment of the present invention the tubing used may have a smaller cross-sectional diameter than the tubing used for conventional CPAP therapy and therefore be less bulky. When used in this invention the less bulky tubing will not be unacceptable solely as a consequence of it introducing pressure swings through the breathing cycle. The tubing used must be capable of supplying to the mask gas flow sufficient to meet the patient's breathing requirements as well as washing out excess CO_2 irrespective of whether it induces pressure swings. The less bulky tubing should facilitate user comfort and ultimately patient compliance.

As previously noted the apparatus is supplied with a patient interface 4. A purpose of the interface 4 is to substantially limit the breathable air of the patient to the gas that is supplied through the apparatus and thereby minimize patient intake of air from alternative sources, such as directly from the ambient environment, which may potentially contain asthma symptom-inducing particulates. The patient interface may be a nasal mask, for example, the MIRAGE™ nasal mask (ResMed Ltd). Alternatively the MIRAGE™ full-face mask, which covers mouth and nose openings of the patient, may be used as a patient interface. The mask is held in position on the head by headgear constructed from hypoallergenic material. A suitable headgear is the MIRAGE™ headgear (ResMed Ltd).

In one form, the patient mask is designed to permit a delivery of breathable gas at a pressure of approximately 1 cm H_2O to 4 cm H_2O above ambient pressure. Because of the relatively low pressures in comparison to the application of nasal CPAP for treatment of OSA, the mask may be of a different design to a mask for treating OSA. Referring to Fig. 3, the sealing membrane 24 for a regular CPAP mask is constructed from silicone rubber of 40 durometer hardness, for example, 595 HC manufactured by DOW and may be 0.3mm to 0.5mm thick. However, because of the lower treatment pressures used in the present invention, in a mask for the present invention, the

thickness may be reduced to 0.1mm to 0.3mm. The thinner membrane may lead to greater patient comfort.

In one form, the mask includes a porous rigid frame 26 to allow CO_2 washout. In another form, the mask is designed to be totally open when the blower is off, acting as an anti-asphyxia valve. This may be accomplished by constructing the mask with a rigid open frame connected to the air delivery conduit, via, in one form, a swivel or ball and socket joint. The mask also contains a membrane with a generally triangular patient-contacting-portion and a bellows shaped non-patient-contacting portion. When the mask is operating under pressure, the flow of air causes the bellows to expand and seal with the air delivery conduit. When the mask is not operating under pressure, the bellows retract, leaving the patient free to breath ambient air. Other suitable masks with anti-asphyxia valves are disclosed in International Publication no. WO/0038772, U.S. Patent No. 5,896,857 and 6,189,532. The disclosures of which are hereby incorporated by reference.

In another form of the invention, the mask includes a lockable swivel or ball and socket joint which enables the air delivery tube to be moved about in a number of different positions, but locked into one of these when desired.

Fig. 4 depicts a polycarbonate mask appropriate for use with the invention. The mask has an addition of two extra vents (only one shown) each consisting of a stainless steel 316 disk 28 secured to the mask shell by way of a silicone grommet which holds the disk in a planer relationship to the mask shell and covers an orifice punched in the mask shell. Each disk is circular, 22 mm diameter, 0.5 mm thick and has 97 circular perforations between its planer sides each perforation being circular 1.2mm x 1.8 pitch. The perforations may be sized to insure adequate CO_2 washout and help to prevent asphyxia in the event of blower failure and/or limit the permissible pressure level in the mask. In this way, the mask can provide to the patient a pressure range between 1.75 cm H_2O and 2.5 cm H_2O. The mask may also be used in trials and studies in relation to other ventilatory assist techniques. For example to compare the effectiveness of a new therapy in a blind trial fashion against minimal or no therapy. In such applications it is worn by the subject in association with the requisite gas conduit and flow generator. In such a configuration the mask will not deliver to the subject a pressure above its

designated top pressure notwithstanding that the flow generator control circuit instructs the flow generator to operate at a level which would deliver a higher pressure had a regular mask been used.

In another form of the patient interface, a mask consisting of a shield with a partial cushion designed to seal on the nose may be utilized. Preferably it is positioned on the nose below the nose bridge, so as to avoid that sensitive part of the patient's anatomy. An illustration of such a mask in accordance with this embodiment can be seen in Fig. 5 and Fig. 6. The sealing membrane 24 is positioned with the intent of preventing gas flow into the user's eyes. The lower part of the mask is open (i.e. is not sealed) and so directs gas downwards over the nares and preferably the mouth so as to provide a 'curtain' of breathable gas. This open lower part 30 of the mask provides washout of exhaled carbon dioxide. It also serves an anti-asphyxia function by providing a safe breathing cavity when the blower is not functioning, thereby negating the need for additional anti-asphyxia components. This interface is designed to be small and light and of minimal impact on the wearer. The intent is to provide a micro atmosphere with a flow of filtered breathable gas that excludes the ambient air to an extent that the patient preferentially breathes the filtered air.

The apparatus of the invention is designed with a controller 12. The controller 12 may include a microprocessor with a medium for programmed instructions or other processor or electronic circuitry to direct the functioning of the apparatus. The controller 12 accepts signals from a flow meter 18, for example, a differential pressure transducer. The controller may also include pressure transducers for sensing pressure levels in the mask. The controller monitors the output from the flow meter, as well as the current to the motor and the number of revolutions per minute of the motor. The controller also controls the display of information on the exterior of the apparatus and is responsive to switches mounted on the exterior.

The controller 12 may be designed to direct the delivery of therapeutic substances, such as a therapeutic gas, drugs and/or supplemental oxygen to the patient interface as further described herein. The device may include a reservoir and pump, or for substances stored under pressure, such as oxygen, a reservoir without a pump. An example of a suitable device for delivery of a therapeutic substance, drug or, oxygen, is

described in US Patent Serial No. 6,029,660 (also disclosed in AU Patent 719758 and PCT AU97/00846). The disclosure of US Patent Serial No. 6,029,660 is hereby incorporated by reference. Such an apparatus is relatively small compared with the prior art. The therapeutic substance delivery devices 14A, 14B administer treatment to the patient under the control of the controller 12 which may control delivery based upon a predetermined schedule and/or the current condition of the patient. The therapeutic substance, drug or supplemental oxygen may be administered directly in the patient interface 4 or alternatively in the blower 2.

In one embodiment, the flow meter 18 measures flow by a differential pressure transducer. Flow of filtered air from the blower passes through a bundle of small tubes 20 aligned in parallel with the flow from the blower. The pressure difference across the bundle varies according to Bernoulli's law. Hence a measure of the flow of air to the mask (raw flow signal) may be calculated. The patient interface 4 includes a deliberate leak through a vent 22 and also typically there is an unintentional leak around the edges of the seal and through other air delivery conduit joints. Since the volumes of air that the patient inhales and exhales over several breaths is approximately equal, an average flow signal over several breaths will provide a measure of the leakage of air from the system. Alternatively, a low-pass filtered air signal, where the filter constant is longer than several breaths, will provide another estimate of the leakage of air from the system. Alternatively, leak flow may be determined according to PCT/AU97/00517. Having determined the long-term average (or low-pass filtered) leak flow, a measure of the instantaneous respiratory airflow may be obtained by subtracting the long-term average signal from the raw flow signal. The respiratory flow signal is a periodic waveform. By convention, inspiration is a positive flow and expiration is a negative flow. Hence it is possible to estimate the transition points between inspiration and expiration from the zero crossing points. In turn this enables the apparatus to synchronize delivery of therapeutic substances, drugs or supplemental oxygen to the inspiratory phase of the breathing cycle and reduce waste of the substance, drug or oxygen. If administered in the blower, then the delivery must be synchronised to account for any propagation delay through the air delivery conduit.

In one form of the invention, the apparatus may be programmed as an asthma attack or asthma-related symptom detector to trigger treatment or to provide a warning of the occurrence of such an attack or such symptoms. In this embodiment, the microprocessor in the device reads the flow signal and determines on a breath-by-breath basis, an index of the roundness or alternatively flatness of the inspiratory portion of the flow time curve. The inspiratory portion of a normal breath waveform has a round shape. If the inspiratory portion of the waveform is flattened or shaped like a square-wave, then it is indicative of partial obstruction of the airway, for example, constriction or narrowing of the bronchus or other asthma-related narrowing of the airways of the lung. One form of flatness index is the RMS deviation of the inspiratory flow curve from a square wave of the same length and area. One form of roundness index is the RMS deviation from a sine wave of the same length and area. Alternatively, the inspiratory flow curve may be scaled to have unit length and area and compared to square and sine waves of unit dimensions. Examples of the formulae for calculating such indices are disclosed in U.S. Patent Serial No. 5,704,345 which is hereby incorporated by reference.

An inspiratory waveform which closely resembles a square wave will have a small RMS deviation from that waveform and hence have a small flatness index. Conversely, it will have a larger RMS deviation from the sine wave and have a larger roundness index. An inspiratory waveform which closely resembles a sine wave will have a small RMS deviation from that waveform and hence a small roundness index. Conversely, it will have a larger RMS deviation from a square wave and have a larger flatness index. Hence the device provides an alarm and logs the information when the roundness and flatness indices indicate the presence of partial obstruction when compared with predetermined thresholds. In this way the device can determine physiologic changes in the user's breathing patterns and indicate the onset of changes consistent with the onset or occurrence of an asthma attack.

In another form of the invention, the apparatus monitors the shape of the expiratory portion of the flow time curve. Abnormally shaped expiratory flow time curves are taken to be indications of the presence of a partial obstruction and the device responds by issuing a warning, logging the event and indicating the possible need for

therapy. For example, this may be accomplished by analyzing an expiratory waveform to determine a flatness or roundness index.

In an embodiment of the invention, the delivery of therapeutic agents or treatments is monitored and recorded together with time and date stamp and other clinically relevant data including user blood oxygen concentration, environmental conditions such as current allergen load and ambient humidity. This data is then processed and made available, say to the clinician, for review. Reported statistics may include frequency and time distribution of airway events (such as deviation from the desired inspiratory or expiratory flow curve) and therapy doses. This data is used for the management of the patient in accessing their response to therapies and as an aid in determining future therapeutic agent dosing. Should there be identified a set of parameters which correlate with an airway event then the device may be programmed to respond by delivery of a predetermined therapeutic response (say by delivery of a therapeutic agent in a predetermined titration regime or ventilatory assistance) and thereby manage the patient's condition in a timely manner. If desired the device can be programmed to act in a proactive manner by recognizing the onset of conditions that have previously resulted in an airway event and deliver the therapeutic response to stabilize the patient prior to the patient having an airway event that warrants a more significant therapeutic response.

The effectiveness of a therapeutics response may be studied by programming the device to only provide a therapeutic response to an identified set of conditions (e.g. patient physiological state or atmospheric conditions or both) on some occasions and not on others. By examination of the monitored data it is possible to determine the effectiveness of the therapeutic response.

In a further embodiment a data management system will build and regularly update templates of patient responses to conditions and therapeutic responses in order to characterize patient responses and thereby provide patient specific data to an expert system decision tree. The decision tree may be used to determine future therapy strategies.

To broaden the system's diagnostic usefulness there may be provided the capacity to eliminate the filtered air reaching the patient so that unfiltered air reaches the

patient. This capacity allows for the ability to identify correlations between environmental contaminates and airway events and therapeutic responses.

In another form of the invention, the apparatus is provided with an attachment for spirometry in the mask. The nose is blocked and the patient is instructed to take a deep breath and blow into the tubing in accordance with known techniques for measuring respiratory function. The device measures the flow and pressure and logs the peak flow and the total volume exhaled during the first 1 second of exhalation. The data from these measurements are available for both the patient and physician.

In one embodiment, the apparatus automatically detects the efficiency or status of the air cleaning device. For example, the controller is configured to monitor the impedance of an air filter by monitoring the power required to deliver a certain pressure and flow or some other measurable function of the blower such as its velocity or r.p.m. As the filter becomes blocked its impedance increases. When the filter impedance has reached a predetermined threshold, a warning is given as an alarm or message display to say that the filter should be replaced. In addition, the apparatus monitors the number of hours of use of the device since some filters ought to be replaced after a fixed number of hours of use. Suitable techniques and algorithms for such monitoring are described in international patent application No. PCT/AU99/0972 (also bearing international publication No. WO00/27457).

In another form of the invention, the apparatus delivers a higher pressure of air to the patient during the inspiratory portion of the patient's breathing cycle. In one form, the higher inspiratory pressure is less than 10 cm H_20. When the apparatus is delivering a therapeutic drug, for example by pumping the drug at pressure from a reservoir, the pressure of drug delivery is controlled to be higher than the mask pressure. Hence when the device delivers a higher mask pressure during the inspiratory portion of the patient's breathing cycle, the apparatus automatically increases the pressure of the drug delivery to be higher than the mask pressure by a predetermined offset.

Although the invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Thus it is to be understood that numerous modifications may be made in the illustrative embodiments of the invention and other

arrangements may be devised without departing from the spirit and scope of the invention

We claim,

1. An apparatus for the delivery of treatment for a patient with asthma, particularly during sleep, comprising:

a blower to generate a flow of breathable gas under pressure, with an inlet for receiving breathable gas to said blower,

a patient interface to provide said flow of breathable gas to the respiratory system of a patient,

a conduit between said interface and said blower to lead said flow of breathable gas to said interface,

a flow meter to generate a flow signal representative of flow to the patient,

a controller to control said blower's generation of said flow of breathable gas based in part on said flow signal, and

a cleaning device to clean said breathable gas to substantially prevent allergen particulates from reaching the patient.

2. The apparatus of claim 1 wherein said cleaning device is a filter.

3. The apparatus of claim 2 wherein said filter is a high efficiency particulate arresting filter.

4. The apparatus of claim 3 wherein said filter includes activated carbon.

5. The apparatus of claim 2 wherein said patient interface is a porous mask to insure CO_2 washout at low pressures that covers the patient's nose openings and has a sealing membrane thickness in the range of 0.1 mm to 0.3 mm.

6. The apparatus of claim 5 wherein said controller controls said blower so as to vary said flow of breathable gas in response to the patient's respiration to maintain a relatively constant pressure at the patient interface.

7. The apparatus of claim 5 wherein said filter is replaceable and wherein said controller is adapted to monitor said blower to assess the filter's condition and to generate a warning when the assessment indicates that said filter should be changed.

8. The apparatus of claim 7 wherein said controller detects the number of hours of use of said blower.

9. The apparatus of claim 7 wherein said controller detects the impedance of said filter to assess the filter's condition as a function of signals from said flow meter.

10. The apparatus of claim 9 wherein said impedance is determined by the controller from the power of said blower in relation to pressure and flow from the blower.

11. The apparatus of claim 10 where said warning is an alarm.

12. The apparatus of claim 7 wherein said controller is configured to control said blower to generate a range of pressure from 1.75 to 2.5 cm H_2O at the mask.

13. The apparatus of claim 2 wherein said controller includes a processor programmed with instructions for controlling an analysis of data from said flow signal to detect a symptom of asthma.

14. The apparatus of claim 13 wherein said analysis of data is a determination of a flow pattern including the steps of:

calculating a shape index from said data; and

comparing said index to a predetermined threshold.

15. The apparatus of claim 14 wherein said shape index is an indicator of the flatness of an inspiratory portion of patient flow.

16. The apparatus of claim 14 wherein said shape index is an indicator of the roundness of an inspiratory portion of patient flow.

17. The apparatus of claim 14 wherein said shape index is an indicator from an expiratory portion of patient flow.

18. The apparatus of claim 1 further comprising a controlled means for delivering a therapeutic substance to supplement said flow of breathable gas to the patient.

19. The apparatus of claim 18 wherein said controller controls said means for delivering the therapeutic substance to limit delivery of the substance during the patient's inspiratory cycle.

20. The apparatus of claim 19 wherein said therapeutic substance is a broncho-dilator.

21. The apparatus of claim 20 wherein said controlled means for delivering a therapeutic substance administers said therapeutic substance at said patient interface.

22. The apparatus of claim 13 further comprising a controlled means for delivering a therapeutic substance to supplement said flow of breathable gas to the patient.

23. The apparatus of claim 22 wherein said controller is further programmed with instructions for controlling a delivery of the therapeutic substance by said controlled means in response to a detection of a symptom of asthma.

24. The apparatus of claim 23 wherein said therapeutic substance is a broncho-dilator.

25. The apparatus of claim 23 wherein said therapeutic substance is a gas.

26. The apparatus of claim 25 wherein said gas is oxygen.

27. An apparatus for the delivery of treatment for a patient with asthma, particularly during sleep, comprising:

a blower with an inlet to supply breathable gas to a patient interface,

a transducer to generate a flow signal representative of flow of the patient ,

a transducer to generate a pressure signal representative of pressure supported by the blower,

a processor to receive data from said flow signal and said pressure signal with programmed instructions for controlling said blower and to detect an asthma symptom from an analysis of said data, and

a filter to substantially remove allergen particulates from the breathable gas flow.

28. The apparatus of claim 27 wherein said filter is a high efficiency particulate arresting filter.

29. The apparatus of claim 28 wherein said filter includes activated carbon.

30. The apparatus of claim 28 wherein said processor controls said blower so as to vary said flow of breathable gas in response to the patient's respiration to maintain a relatively constant pressure at the patient interface.

31. The apparatus of claim 29 wherein said patient interface is a porous mask to insure CO_2 washout at low pressures that covers the patient's nose openings and has a sealing membrane thickness in the range of 0.1 mm to 0.3 mm.

32. The apparatus of claim 31 wherein said processor is further programmed with instructions to assess filter status and to generate a warning when said assessment indicates that the filter should be changed.

33. The apparatus of claim 27 further comprising a controlled means for delivering a therapeutic substance to supplement said flow of breathable gas to the patient.

34. The apparatus of claim 33 wherein said processor is further programmed with instructions for controlling a delivery of the therapeutic substance by said controlled means in response to a detection of a symptom of asthma.

35. The apparatus of claim 34 wherein said therapeutic substance is a broncho-dilator.

36. The apparatus of claim 34 wherein said therapeutic substance is a gas.

37. The apparatus of claim 36 wherein said gas is oxygen.

38. A method for treating a patient with asthma, particularly during sleep, comprising the steps of:

delivering a controlled supply of breathable air to a patient,

providing a patient interface that substantially limits the patient's breathable air to the controlled supply of breathable air when it is being supplied through the interface,

cleaning said breathable air in conjunction with the delivery of said breathable air to the patient to substantially remove allergen particulates from said air before said patient inhales said allergen particulates,

monitoring air flow of the patient, and

analyzing said air flow to detect a symptom of asthma.

39. The method of claim 38 wherein said patient interface is a porous mask to insure CO_2 washout at low pressures that is adapted to cover the patient's nose openings.

40. The method of claim 38 wherein said patient interface permits a breathable flow of ambient air when said controlled supply of breathable air ceases.

41. The method of claim 39 wherein said controlled supply of breathable air varies in response to the patient's respiration to maintain a relatively constant pressure at the patient interface.

42. The method of claim 41 wherein said controlled supply of breathable air is varied in a range of pressure from 1.75 to 2.5 cm H_2O at the mask.

43. The method of claim 42 wherein said filter is a high efficiency particulate arresting filter.

44. The method of claim 43 wherein said filter includes activated carbon.

45. The method of claim 41 further comprising the step of administering a therapeutic substance to the patient through the patient interface in response to said detection of a symptom of asthma.

46. The method of claim 44 wherein said therapeutic substance is a broncho-dilator.

47. The method of claim 45 wherein said therapeutic substance is a gas.

48. The method of claim 47 wherein said gas is oxygen.

49. The method of claim 43 further comprising the step of assessing the condition of the filter to determine whether the filter should be changed.

50. The method of claim 49 wherein said step of assessing involves calculating the impedance of the filter.

51. The method of claim 50 wherein said impedance is a function of the blower's power consumption.

52. The method of claim 43 wherein said step of analyzing said air flow to detect a symptom of asthma includes the sub-steps of:

calculating a shape index from data representing a portion of said air flow; and

comparing said index to a predetermined threshold.

53. The method of claim 52 wherein said shape index is an indicator of the flatness of an inspiratory portion of patient flow.

54. The method of claim 52 wherein said shape index is an indicator of the roundness of an inspiratory portion of patient flow.

55. The method of claim 52 wherein said shape index is an indicator of the flatness of an expiratory portion of patient flow.

56. The method of claim 52 wherein said shape index is an indicator of the roundness of an expiratory portion of patient flow.

57. An apparatus for the delivery of treatment for a patient with asthma, particularly during sleep, comprising:

a blower to generate a flow of breathable air under pressure, with an inlet for receiving breathable gas to said blower,

a patient interface to provide said flow of breathable air to the respiratory system of a patient,

a conduit between said interface and said blower to lead said flow of breathable air to said interface,

a cleaning device to clean said breathable air to substantially prevent allergen particulates from reaching the patient,

wherein said patient interface includes (1) a shield portion to direct a curtain flow to the patient, (2) a sealing membrane to prevent said flow to the patient's upper face and (3) an open cavity to permit a sufficient transfer of ambient air to the patient to prevent asphyxia when said blower ceases generating said flow of breathable air,

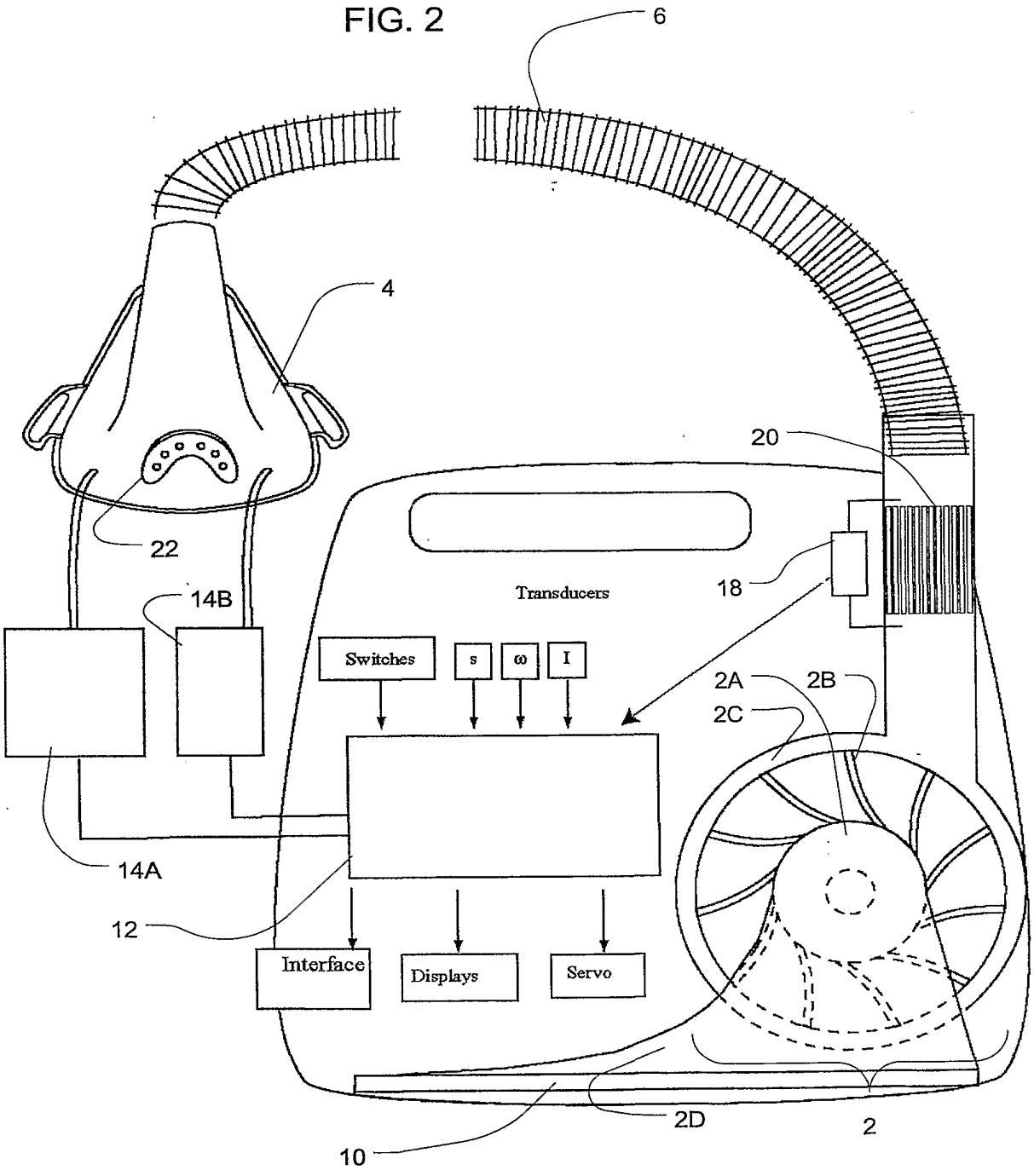
58. The apparatus of claim 57 wherein said cleaning device is a filter.

59. The apparatus of claim 58 wherein said filter is a high efficiency particulate arresting filter.

60. The apparatus of claim 59 wherein said flow of breathable air is supplied in an approximate range of pressure from 1.75 to 2.5 cm H_2O.

FIG. 1
PRIOR ART

FIG. 2


6
4
20
22
Transducers
18
14B
Switches
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2C
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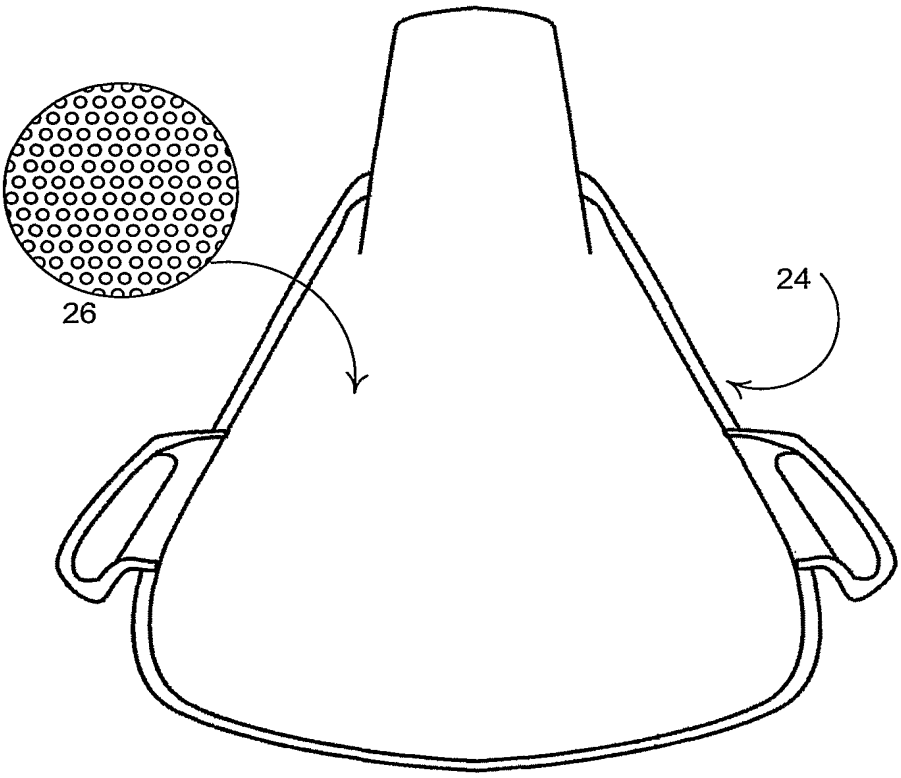
Interface
Displays
Servo
2D
2
10

FIG. 3



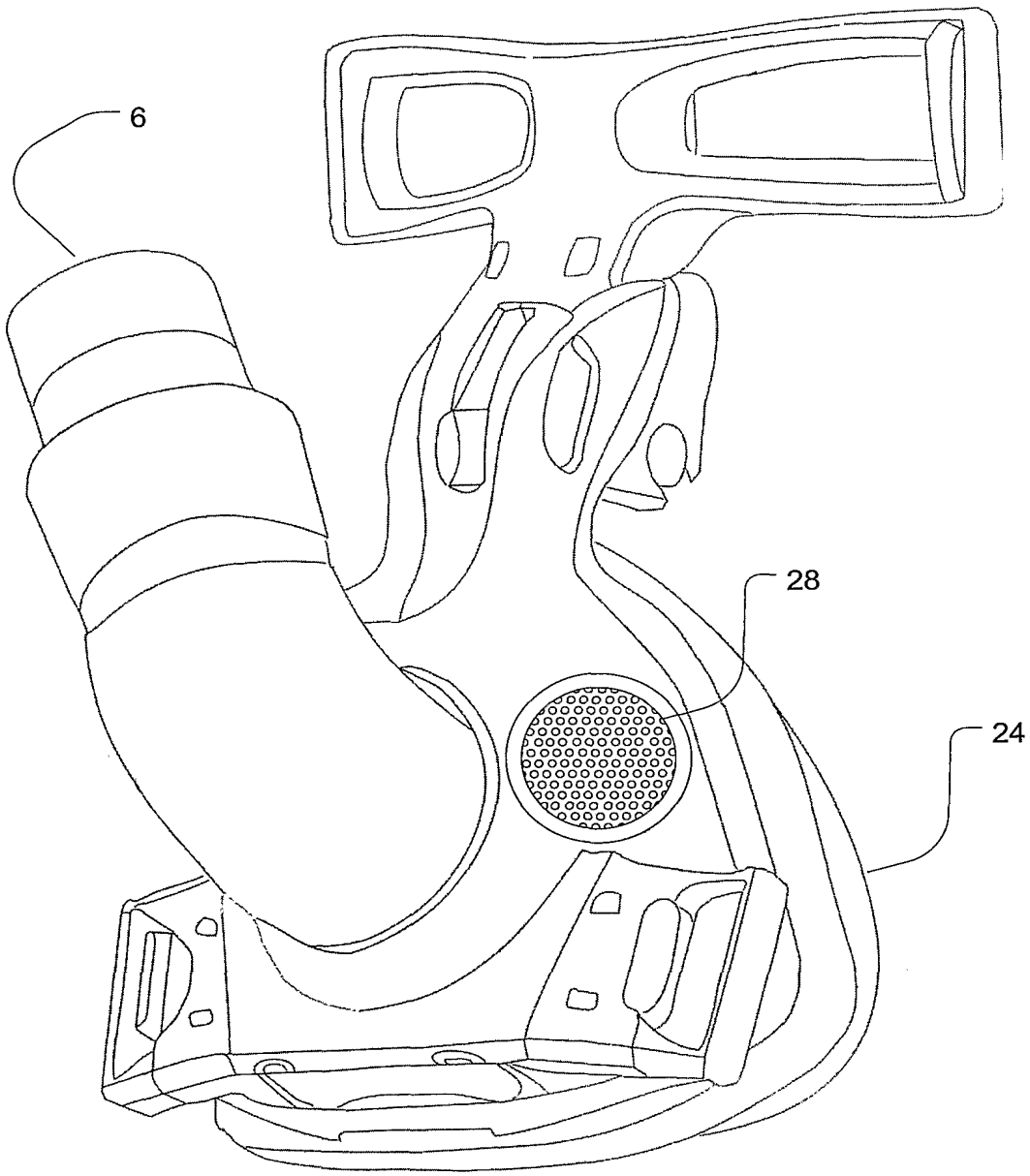


FIG. 4

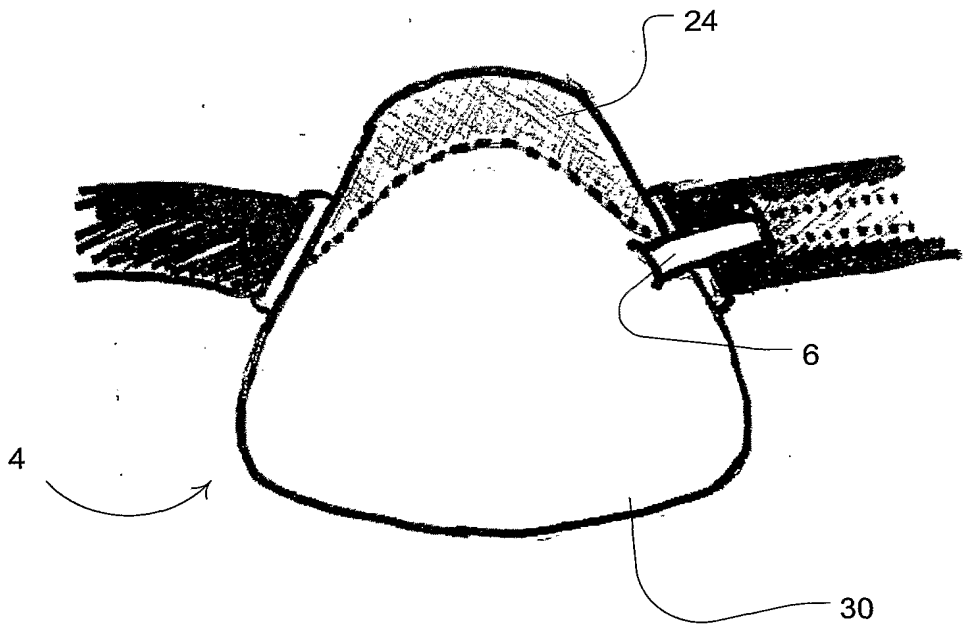


FIG. 5

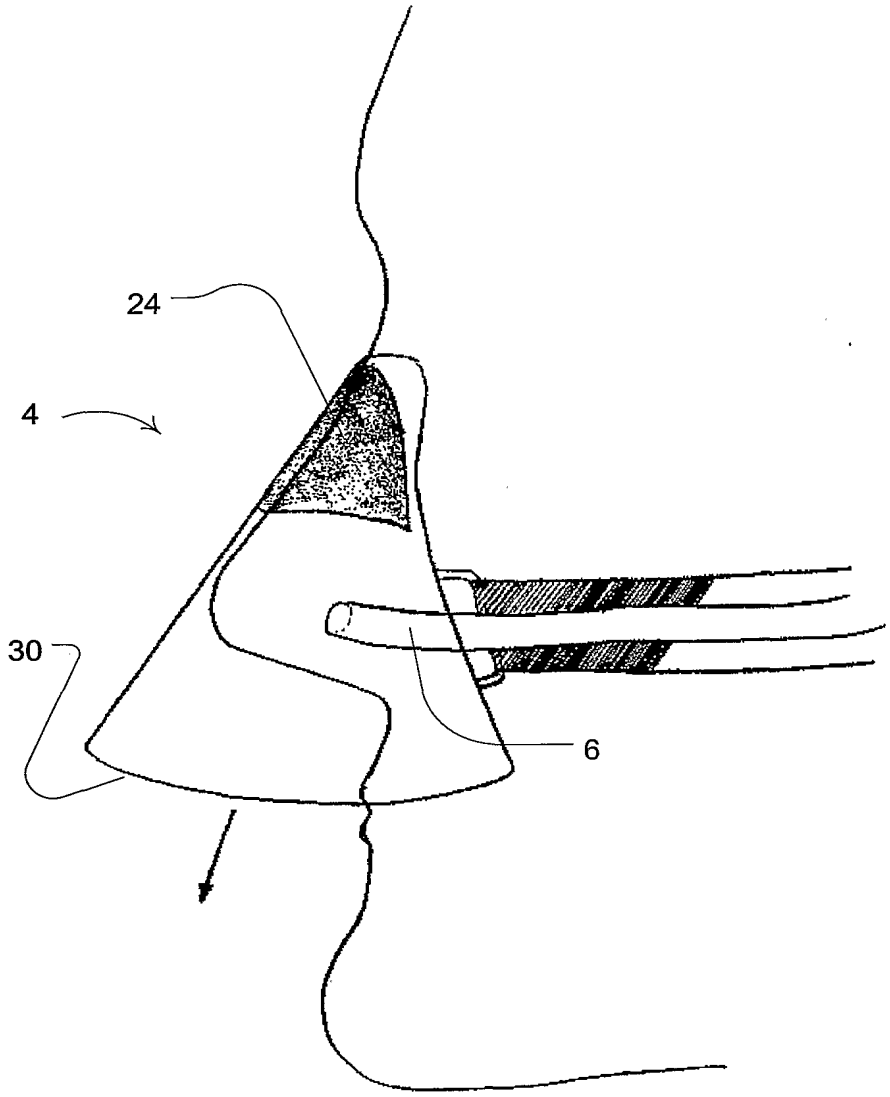


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU02/00161

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

REFER ELECTRONIC DATABASE CONSULTED BELOW.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI & Keywords: filter, filtrate, clean, reduce, remove, separate, arrest, dirt, allergen, dust, pollen, pollution, asthma, mask, interface, flow and similar terms (Note: DWPI includes WPAT, WPI, WPIL)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2300814 A (OMERESAN DEDIARE) 20 November 1996 whole document	1-26
A	EP 241188 A1 (RACAL SAFETY LIMITED) 14 October 1987	
A	EP 334555 A2 (SABRE SAFETY LIMITED) 27 September 1989	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 April 2002	26 APR 2002
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **Geoff Sadlier** Telephone No : (02) 6283 2114

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU02/00161

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99/12635 A1 (KORMAN) 18 March 1999	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU02/00161

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See supplemental box.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The specification does not comply with Section 40(4). The claims do not relate to one invention only (or to a group of inventions so linked as to form a single general inventive concept). In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to be "special technical features". These are features which potentially distinguish the claimed combination of features from the prior art. Where different claims have different special technical features they define different inventions. I have found that there are different inventions as follows:

(1) Claims 1-26 are directed to an apparatus for the delivery of treatment for a patient with asthma comprising a blower, patient interface and cleaning device. It is considered that a flow meter for controlling the blower comprises a first "special technical feature".

(1) Claims 27-56 are also directed to an apparatus for the delivery of treatment for a patient with asthma comprising a blower, patient interface and cleaning device. It is considered that an asthma detection means comprises a second "special technical feature".

(2) Claims 57-60 are also directed to an apparatus for the delivery of treatment for a patient with asthma comprising a blower, patient interface and cleaning device. It is considered that the interface arrangement comprises a third "special technical feature".

These groups are not linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is the general subject matter of an apparatus for the delivery of treatment for a patient with asthma comprising a blower, patient interface and cleaning device. However this concept is not novel in the light of GB 2300814 A (OMERESAN DEDIARE). Therefore these claims do not relate to one invention only, a posteriori.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU02/00161

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
GB	2300814	NONE					
EP	241188	NONE					
EP	334555	GB	2215615	US	4886056		
WO	9912635	AU	63320/98	CA	2259128	EP	929356
		US	6119689				

END OF ANNEX